

to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]

Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with § 381.115 or § 381.205, except that poultry products inspected and passed and identified as such under the laws of an

“at least equal” State or territory listed in § 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in § 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary

by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in § 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law.

Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in accordance with instructions issued by the Administrator.¹

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its

quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe: *Provided*, That subsequent to approval of the total plant quality control system by the

¹Further information concerning sampling plans which have been adopted for specific products may be obtained from the Circuit Supervisor. These sampling plans are developed for individual products by the Washington staff and will be distributed for field use as they are developed. The type of plan applicable depends on factors such as whether the product is in containers, stage of preparation, and procedures followed by the establishment operator. The specific plan applicable depends on the kind of product involved.

Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) *Partial Quality Control Programs.*

(1) Any owner or operator of an official establishment preparing poultry products who is required to have a quality control program for a product, operation, or part of an operation shall make the written program and data and information generated by the program available to all Program employees.

(2)(i) This quality control program shall include, as appropriate for the product, operation, or part of an operation which the program concerns, detailed information on: raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will be taken to prevent recurrence of a loss of control, and the nature of the corrective action—ranging from the least to the most severe.

(ii) This quality control program shall ensure that the product, operation, or part of an operation which it concerns is in control and that applicable product or label limits are being met. Process control is to be determined by generally recognized statistical process control procedures.

(e) *Evaluation and Approval of Quality Control Systems.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) of this section or § 381.149 of this subpart. If it is determined by the Administrator, on the basis of the evaluation, that the total quality con-

trol system or quality control system for irradiation facilities will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulation thereunder, the total quality control system or quality control system for irradiation facilities will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system in accordance with this notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or quality control system for irradiation facilities to assure compliance with the requirements of the Act and regulations thereunder. With the exception of a quality control system for irradiation facilities, as specified in § 381.149 of this subpart, the Secretary shall continue to provide the Federal inspection necessary to carry out the responsibilities of the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as

required by subparts M and N of this part.



(g) *Termination of Quality Control Systems.* (1) The approval of a total plant quality control system may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or a quality control system for irradiation facilities may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the es-

tablishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total establishment quality control system has been terminated in accordance with the provisions of this section, an application and request for approval of the same or modified total establishment quality control system will not be evaluated by the Administrator for at least 6 months from the termination date.

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

(h)(1) *Operating Schedule Under Total Plant Quality Control.* An official establishment with an approved total plant quality control system may request approval for an operating schedule of up to 12 consecutive hours per shift. Permissions will be granted provided that:

(i) The official establishment has satisfactorily operated under a total plant quality control system for at least 1 year.

(ii) All products prepared and packaged, or processed after the end of 8 hours of inspection shall only be a continuation of the processing monitored by the inspector and being conducted during the last hour of inspection.

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and

shall specify how the conditions in §381.145(h)(1) have been or will be met.

(3) *Monitoring by Inspectors.* In order to verify that an establishment is preparing and shipping product in accordance with the approved total plant quality control system and the Act and regulations after the 8 hours of inspection, the official establishment may be provided overtime inspection services at the discretion of the circuit supervisor and charged for such services.

(i) Containers with substances approved for use in the processing of products in §381.147(f)(3) of this subchapter which enter any official establishment for use in poultry scald water shall, at all times, while they are in such establishment, bear labels showing the chemical names of the substances in such preparations. In the case of preparations containing substances which may be used under §381.147(f)(3) only in limited amounts, the container labels shall also show the percentage of each such substance in the preparation and shall provide dilution directions which prescribe the maximum allowable use concentration of the preparation.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015)

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§381.146 Sampling at official establishments.

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

§381.147 Restrictions on the use of substances in poultry products.

(a) All ingredients and other substances used in the processing or handling of poultry products at official establishments shall be such as will not result in adulteration or misbranding of the poultry products.

(b) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment, or imported from a foreign country listed in §381.196(b), and inspected and passed, in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed for use as human food when handled in a manner approved by the Administrator in specific cases, and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements under the Federal Food, Drug, and Cosmetic Act.

(c) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.

(d)(1) Carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States only in an official meat packing establishment, or imported, and were inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (subchapter A of this chapter) and are so marked.

(2) Pork from carcasses or carcass parts, used as an ingredient in poultry products, that has been found free of trichinae, as described under §318.10 (a)(2), (e) and (f) of the Federal meat inspection regulations (9 CFR 318.10 (a)(2), (e) and (f)), is not required to be treated for the destruction of trichinae.

(3) Poultry products containing pork muscle tissue which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 381 of the regulations in subchapter C, or upon subsequent reevaluation of the product, would be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product or otherwise, shall be effectively heated, refrigerated, or cured to destroy